Exhibit B

Exhibit 3

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.,
Civil Action No. 01-12257-PBS

Exhibit to the July 24, 2009, Declaration of George B. Henderson, II
In Support of United States' Common Memorandum of Law in Support of Cross-Motions for Partial Summary Judgment and in Opposition to the Defendants' Motions for Summary Judgment

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	
THIS DOCUMENT RELATES TO:	)	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS; and	)	MDL No. 1456 Master Case No. 01-12257-PBS Subcategory Case No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	)	Hon. Patti B. Saris

DECLARATION OF CAROLYN HELTON

I, Carolyn Helton, do hereby declare and state as follows:

1. I am currently employed by CIGNA Government Services ("CIGNA").[1] During the period 1993 through September 2006, CIGNA was the Durable Medical Equipment Regional Carrier ("DMERC") for Region D. Except to the extent specifically noted in this declaration, I have personal knowledge of the matters stated herein.

2. I work at the CIGNA offices at Two Vantage Way, Nashville, Tennessee 37228. I have worked for CIGNA in its capacity as a Medicare Part B carrier, DMERC, or DME Medicare Administrative Contractor (MAC) since 1991. I currently hold the

[1] CIGNA Government Services is a subsidiary of CIGNA Corporation.

position of Claims Service Analyst for HCPCS and Pricing. I have held that position since 1999. I have given deposition testimony in this litigation.

Medicare Part B; DMERC; HCPCS Codes

3. Medicare Part B has included a durable medical equipment ("DME") benefit, including certain drugs used in connection with items of DME. One item of DME that is covered by Medicare Part B is the nebulizer, which is a device used to administer medications for the treatment of lung diseases such as chronic obstructive pulmonary disease. Drugs used with a nebulizer, and which are covered by the DME benefit, include albuterol, and ipratropium bromide. These are also sometimes referred to as inhalation therapy drugs. Medicare Part B reimbursement for covered drugs is based on the allowable amount, which is the lower of the amount calculated by the carrier or the amount submitted by the provider in the claim.

4. Before 1993, reimbursement under Medicare Part B, including coverage for DME supplies, was administered by a number of different Medicare carriers nationwide. Effective in 1993, the Health Care Finance Administration ("HCFA"), now known as the Center for Medicare and Medicaid Services ("CMS"), consolidated the administration of the Medicare DME benefit in four newly-established DMERCs. CIGNA was selected as the DMERC for Region D, covering Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Northern Mariana Islands, Oregon, South Dakota, Utah, Washington, and

Wyoming. The DMERCs selected for the other regions were Travelers Insurance Company (later HealthNow) (Region A); Associated Insurance Companies, Inc. – AdminaStar Federal (Region B), and Palmetto GBA (Region C).

5. I first began work at CIGNA in 1991 as a claims processor in connection with CIGNA's work as a Medicare Part B carrier for North Carolina. In June 1993, I transitioned as a claims processor to the new unit at CIGNA that was established to carry out CIGNA's new responsibilities as the DMERC for Region D. From late 1994 until 1999, I held the position of pricing analyst. During that time the pricing analysts shared the responsibilities of determining payment amounts for DME drugs, including inhalation therapy drugs. In 1999, I assumed the position of Claims Service Analyst for HCPCS and Pricing. The primary responsibility for determining payment amounts for DME drugs was transitioned to me as part of this new position. In September 2006, I was transferred to a unit of CIGNA that administered the Medicare Part B local carrier contract, where I served as a Claims Services Analyst for the technical team. In May of 2007, I transitioned to my current position, Claims Service Analyst for HCPCS and Pricing for the Jurisdiction C DME MAC contract.

Methods Used To Determine the Allowable Amount

6. During the period 1994 through 1998, I shared responsibility with several other CIGNA employees for calculating pricing for Medicare-covered drugs used with DME, including inhalation drugs. From 1999 through 2006, I had primary responsibility

for this pricing work. In the paragraphs below, I describe how I determined the allowable amounts for those drugs, and I explain whether and how the allowed amounts would have differed if alternative AWPs had been published for certain products. I understand that the relevant time period is generally 1996 through December 31, 2003; therefore I generally limit my discussion to that time period.

7. Most Medicare Part B drugs are classified according to the Healthcare Common Procedure Coding System (HCPCS). Medicare assigns individual HCPCS codes for most drugs. These codes have usually included a prefix of "J" or "K." The HCPCS codes are used in the determination of allowable amounts, and Medicare Part B payments for covered drugs are made on the basis of HCPCS codes. Beginning April 1997, a number of new temporary HCPCS codes (beginning with the letter "K") were established for inhalation therapy drugs. These codes included modifier codes ("KO," "KP," and "KQ") with associated calculations designed to determine appropriate allowable amounts when two or more drugs were compounded.

8. During the relevant time period the Health Care Finance Administration ("HCFA"), later known as the Center for Medicare and Medicaid Services ("CMS"), periodically issued guidance to the DMERCs regarding how to determine the allowable amounts for DME drugs. I followed that guidance.

9. I performed drug pricing calculations using average wholesale price (AWP) data that I retrieved from the publishing compendia, Red Book. This publication provided

the national drug code (NDC) and the corresponding AWP for each listed drug product. In general, I performed drug pricing updates quarterly, although in the early years (approximately 1993 - 1997) updates were sometimes done on an as-needed basis or as additional pricing information was received. Especially after about 1997, the four DMERCs coordinated their quarterly pricing determinations to ensure national consistency.

10. Generally, to ascertain the allowable amount for a particular DME drug, I first determined which NDCs were covered under a particular HCPCS code. I used the Red Book to do this, comparing candidate NDCs from the Red Book against the narrative description of the HCPCS code and selecting those NDCs that fell within the narrative description. I generally did not select drugs with special sized packaging, or convenience items such as flip-top vials, carpu-jets, tubes, and others. Such items are not considered necessities, and typically inflate the price. The policy to not select such items for inclusion in arrays was developed and implemented over a period of time by DMERC representatives in consultation with HCFA officials. The restrictions now appear in CMS's Internet-Only Manual (IOM), Publication 100-04, Medicare Claims Processing Manual (Chapter 17, § 20.5.5).[2]

[2] This manual is available on-line at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912.

11. Using the NDCs selected for the relevant HCPCS code, I then created an array of prices that included the AWP for each selected NDC, using Red Book data. I converted each AWP price to a unit price, so that I had a common measure of price. Using this array, I determined the median AWP for the NDCs of the drug products that fit the description of the HCPCS code. If there was only one NDC with a published AWP in the array, I selected that price as the median. If there was an odd number of NDCs in the array, I selected the middle NDC and its corresponding price. If there was an even number of NDCs in the array, I took the average of the middle two NDCs' prices to achieve a median. Before 1997, my arrays were generally handwritten. Beginning in 1997, I began using a spreadsheet format. The spreadsheets evolved over time so that, by about 1999, the necessary calculations for determining the median were programmed into the spreadsheet.

12. CIGNA's methodology for creating these arrays, and determining allowable reimbursement rates changed in the 1996-2003 period, in accordance with changing regulations or CMS instructions. The paragraph below outlines these changes in greater detail.

13. From 1994 through December 31, 1997, CIGNA calculated the allowable reimbursement rate as 100% of the median AWP of the generic forms of the drug (unless, as stated above, only a brand drug was available). Beginning January 1, 1998, as a result of the Balanced Budget Act of 1997, the DMERCs began paying providers at ninety-five

percent of the median AWP. Accordingly, for quarters beginning January 1998, I calculated the allowable fee by multiplying the median AWP by 0.95. In addition, HCFA instructed the DMERCs that if a brand name product AWP was lower than the median of the generic AWPs, the DMERC should calculate a new median with the brand included in the array.[3] This last-mentioned instruction changed approximately one year later when HCFA issued instructions that the allowable amount was to be determined as the lower of the median of the generic sources of the drug or the lowest priced brand name AWP (as opposed to re-calculating the median with the brand AWP included).[4]

14. Once I determined a new allowable amount for a HCPCS code, I entered the new or updated price into the electronic claims processing system used by the DMERCs for paying Part B claims, referred to as the ViPS Medicare System. Once a new or updated allowable amount was entered, the ViPS Medicare System used that price for determining the reimbursement of all applicable Medicare Part B claims that had not already been processed through the pricing part of the system.

15. Effective January 1, 2004, the payment methodology for Part B covered drugs, including most DME drugs, changed as a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

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[3] HCFA Transmittal No. AB-97-25 (January 1998).

[4] HCFA Transmittal No. AB-98-76 (December 1998).

Ipratropium Bromide

16. Attached as Exhibit A are copies of the CIGNA DMERC arrays for Ipratropium Bromide Inhalation Solution, 0.2%, unit dose, from 1996 through the fourth quarter of 2003. I used these arrays to calculate the allowed amounts for J7645, K0518, and J7644. Code J7645 was the HCPCS code for this drug from January 1, 1995, through March 31, 1997. HCPCS code K0518 applied from April 1, 1997, through December 31, 1999; and HCPCS code J7644 applied from January 1, 2000, through the present. Some of the original arrays are in paper format; some are in electronic Excel spreadsheet format. The copies in Exhibit A are true and accurate with the sole exception of the bates-stamp numbers or the file source information described below.

17. The first three arrays in Exhibit A that pre-date the second quarter ("Q2") of 1999 are from my paper files. Bates-stamp numbers have been added. The originals of these arrays did not include the NDC numbers of the drugs that I included in the arrays. In preparation for deposition testimony in this litigation, I created annotated versions of the three paper arrays that included Dey and Roxane products, in which I added the NDC numbers for the Dey and Roxane products. I did this by looking in the appropriate Red Book publication (which I still have access to, except where noted), and finding the NDC corresponding to the product shown in the array. These annotated arrays are marked with bates-stamp numbers AWQ039-044 through AWQ039-046 and

are attached as Exhibit B. The NDC numbers that I added accurately reflect the NDCs of the Dey and Roxane products that I included in the original arrays.

18. Based on the notations and other information in the array, and based on my experience, I can tell that the first array (AWQ021-0097) was used by CIGNA to determine the allowable amount for J7645 for the period 1996 Q3 through 1997 Q1. (None of the Dey or Roxane products appears in that array.) Similarly, I can tell that the array at AWQ021-0219 was used to determine the allowable amount for K0518 for the period 1997 Q2 through 1998 Q2. The array at AWQ021-0220 was used to determine the allowable amount for K0518 for the period 1998 Q3 through 1998 Q4. The array at AWQ021-0221 was used to determine the allowable amount for K0518 for 1999 Q1. No CIGNA arrays are missing for J7645, K0518, and J7644 for the period 1996 through December 31, 2003. I used Red Book as the source of AWPs for all of the arrays in Exhibit A.

19. The arrays in Exhibit A for K0518 and J7644 covering 1999 Q2 through 2003 Q4 are from electronic spreadsheet arrays that were produced in native format; therefore they do not have bates-stamp numbers. To facilitate identification, the originals have been altered to add a footer that identifies the source of the file by reference to a bates-stamp number identifying the CD Rom, the pathway to the electronic Excel file, and the name of the worksheet containing the array. Except for these footers, the arrays are true and accurate copies of the originals. The original electronic spreadsheet files

contain separate worksheets for specific quarters, and the electronic "tab" for each worksheet is named in the electronic file according to the year and quarter for which the array was created. The tab name (which cannot be imaged in a paper or pdf version) has been included in the identifying footers that have been added to the copies in Exhibit A. Therefore the footer in each array accurately identifies the year and quarter covered by the array.

20. All of the arrays from 1997 Q2 through 2003 Q4 show the same median generic price, $3.52, for K0518/J7644. Therefore, for these HCPCS codes with the KO and KP modifiers, I would expect that CIGNA Medicare claims data would show many claims paid on the basis of a per-unit allowed amount of $3.52 from approximately the beginning of the second quarter of 1997 through the end of 1997, and then show many claims paid on the basis of an allowed amount of $3.34 (which is 95 percent of $3.52) from approximately January 1, 1998, through the end of 2003. I would also expect to see a small or modest number of claims paid on the basis of allowed amounts lower than the $3.52 and $3.34 amounts, because Medicare paid the lower of the amount calculated by the DMERC or the billed amount. I would expect to see zero or almost zero claims paid on the basis of allowed amounts higher than the $3.52 and $3.34 amounts referenced above.

Effect of Alternative AWPs

21. I have been asked by counsel for the Department of Justice to determine, for the arrays in Exhibit A, how much lower the published prices for Dey's ipratropium bromide products would have to be in order to affect the Medicare allowable amount. I have been asked to do the same with respect to the Roxane products. Additionally, I have been asked to determine the minimum reduction in the prices for both the Dey and Roxane products that would have resulted in a lower Medicare allowable amount.

22. To do this, I have substituted different numbers for the Dey and/or Roxane AWPs to see what changes will affect the median and what changes will not. To avoid rounding issues, I have simplified my task by multiplying the original Dey and/or Roxane AWPs (as shown in the original arrays) by .99 and entering those alternative prices in re-created arrays. In many instances, this reduction of just one percent results in a lower allowable amount.

23. With respect to Dey, for the periods 1997 Q2 through 2001 Q3, any reduction of one percent or more in the AWPs of the Dey products listed (whether the AWP is expressed as a unit price or as the package price) would lower the median and therefore the Medicare allowed amount.

24. With respect to Roxane, for the periods 1997 Q2 through 2001 Q3, any reduction of one percent or more in the AWPs of the Roxane products listed, excluding the NovaPlus products, (whether the AWP is expressed as a unit price or as the package

price) would lower the median and therefore the Medicare allowed amount. For the period 2001 Q2 through 2003 Q4, when Roxane's NovaPlus ipratropium bromide products (having NDCs beginning with 00054-8402) appeared in the brand portion of the arrays, any reduction of one percent or more in the AWPs of the six Roxane products would cause the lowest price brand product (NovaPlus) to be lower than the median of the generic products, and therefore would cause the Medicare allowed amount to be lower.

25. With regard to the period 1997 Q2 through 2003 Q4, any reduction of one percent or more in the AWPs of both the Dey and Roxane ipratropium bromide products would reduce the Medicare allowed amount, regardless of whether one changes the NovaPlus prices.

Red Book AWPs

26. As indicated earlier in this declaration, the AWPs shown in the arrays in Exhibit A were recorded from Red Book publications. Attached as Exhibit C is a summary showing the AWPs for the Dey and Roxane ipratropium bromide products as recorded in the CIGNA arrays identified above, for the years and quarters indicated. Exhibit C accurately states the AWPs published in the Red Book for the time period covered by the arrays. As can be seen, the Red Book AWPs of the Dey and Roxane products did not change throughout the time period.

Roxane NovaPlus As a Brand

27. In CIGNA's DME pricing arrays for J7644, CIGNA consistently classified the Roxane Ipratropium Bromide NovaPlus products as brands. These products first appeared in the CIGNA arrays in 2001 Q2 and remained in the arrays through 2003 Q4.

28. In HCFA Transmittal No. AB-98-76, a copy of which is attached to this declaration as Exhibit D, the Health Care Finance Administration (now CMS) instructed the DMERCs, "A 'brand name' product is defined as a product that is marketed under a label name that is other than the generic chemical name for the drug or biological."

29. CIGNA classified products as brands or generics based on the product name. It was our determination that "Ipratropium Bromide NovaPlus" is a label name other than the generic chemical name.

30. Other "NovaPlus" products appeared in other CIGNA pricing arrays. CIGNA also classified those other products having the "NovaPlus" name as brands. Attached as Exhibit E are three examples of CIGNA arrays for drugs other than ipratropium bromide that include NovaPlus. As one can see, I treated those NovaPlus products as brands.

31. During the period 2001 Q2 through 2003 Q4, when the Roxane NovaPlus products were in the arrays, CIGNA generally used the quarterly Red Book CD-ROM as the source of information for preparing arrays, including for determining whether to treat a product as a brand or generic. In the search database of the CD-ROM we selected the

generic name of the drug (shown in lower case letters) in order to retrieve all versions of the drug, both brand and generic. The search function would retrieve the brand and generic products into a Product Information Screen. The Product Information Screen of the quarterly CD-ROM did not use typeface or font to distinguish between brands and generics. The typeface and font in the Product Information Screen was the same for both brands and generics. Attached as Exhibit F is an example[5] of how drug product information appeared in the Product Information Screen of the quarterly Red Book CD-ROM. In this example, CIGNA would have classified four products as brands based on the product name. The four products are Atrovent and the three Ipratropium Bromide NovaPlus products manufactured by Roxane.

Potential Impacts On Array Calculations

32. I have previously produced in this litigation CIGNA arrays for HCPCS codes covering, among other drugs, albuterol sulfate and ipratropium bromide.[6] Using these arrays, it is not difficult to determine whether and how allowable amounts would have changed if certain lower AWPs had been published for specific NDCs. One simply re-calculates the allowed amount using the alternative AWPs. In the following paragraphs I illustrate with specific examples how the allowable amounts for the HCPCS

[5] This particular document did not originate from CIGNA.

[6] Copies of paper DMERC arrays for these drugs (with annotations giving NDC numbers) are reproduced with bates-stamp numbers AWQ039-025 - AWQ039-036, and AWQ039-044 - AWQ039-046. Copies of electronic spreadsheet arrays are reproduced in a CD ROM marked AWQ020 CD#1.

codes for albuterol sulfate and ipratropium bromide would have changed if the published prices for the drugs sold by both Dey, Inc. and Roxane Laboratories, Inc. had been lower.

Albuterol Sulfate, Unit Dose

33. Attached as Exhibit G is a true copy of a CIGNA pricing array for K0505, for the third quarter of 1999. K0505 was a temporary HCPCS code for drugs falling within the narrative description "Albuterol, Inhalation Solution Administered Through DME, Unit Dose Form, per milligram." I prepared this array, as indicated by my initials ("CH") in the far right column. In the array, Dey's reported AWPs are $30.25 for packages of 25, $36.30 for packages of 30, and $72.60 for packages of 60. These prices translate to a unit dose cost of $0.49 for each of Dey's drugs. The generic median AWP per unit dosage for the entire array also comes to $0.49. The allowed amount is 95% of this, or $0.47.

34. I have been asked to assume, as a hypothetical, that the published AWPs for the three Dey products in the array were false, and that true AWPs for those products at the time were $7.82, $9.10, and $18.31, for the packages of 25's, 30's, and 60's, respectively. These package prices translate to unit prices of $0.13, $0.12, and $0.12, respectively. Although these alternative prices are much lower than (about one-fourth of) the prices that were published, if one were to substitute these for the AWPs shown in the array, there would be no change in the median, and hence no change in the allowed amount. This is because of the presence of numerous other NDCs in the array with unit

price AWPs at or slightly above the AWPs published for the Dey products, i.e., within the range of $0.49 to $0.53. Changing the AWPs of just the Dey products does not change the median.

35. Of course, if it were proven that AWPs for other manufacturers' products in this array were also false, and if lower prices were substituted for those as well, the result could be very different. For example, if it were shown that all of the eleven manufacturers with published AWPs at or above Dey's AWPs inflated their AWPs to the same extent as assumed for Dey (i.e., that true AWPs were one-quarter of the published AWPs), this, in combination with alternative prices for the Dey products, would change the median unit price to $0.13, and the allowable amount to 95% of that, or $0.12. The attached Exhibit H is a recalculated array showing this. The difference between $0.12 and the allowed amount in the original array, $0.47, which is $0.35, would represent the amount of the overpayment caused by all of these hypothetically-false AWPs, for one unit of this drug, 80 percent of which would be paid by Medicare.

36. If one were to make the same assumptions as in the preceding paragraph, but instead evaluate the impact of each manufacturer separately, and then take the sum of those individual impacts, the result would not be a $0.35 overpayment, but would be zero. This is because, as illustrated previously, changing the AWPs of any single manufacturer in the array has no impact on the allowed amount.

Ipratropium Bromide

37. Attached as Exhibit I is a true and correct copy of a CIGNA array for K0518, a HCPCS code for Ipratropium Bromide, Inhalation Solution Administered Through DME, Unit Dose Form, per milligram. Exhibit J is a copy of the same array, except that I have annotated the array to specify the NDC numbers of the Dey and Roxane products, using information from the 1998 Red Book.[7] This particular array is for the fourth quarter of 1998. I created the array, as indicated by my initials in the right-hand column for the third quarter of 1998. Another pricing analyst, denoted by the initials "MR," reviewed the third quarter array and the Red Book monthly updates and indicated that there were no changes to the information through 09/30/1998.

38. The array includes six products and their corresponding AWPs obtained from Red Book, and it includes the price per milligram that I calculated from the package price. Two of the products in this array are Dey products; three are Roxane products; and one is a Compumed product. The median unit price is the average of the third and fourth highest prices. Because five of the six prices are $3.52, the median is equal to $3.52. The calculated allowed amount for the KO and KP modifiers is 95% of the median, or $3.34.

39. I have been asked to assume, hypothetically, that Dey and Roxane reported falsely inflated AWPs for their products, and to calculate the allowed amounts in three

[7] The HCPCS code K0518 was in effect from April 1, 1997, through December 31, 1999, and included KO, KP, and KQ modifiers. Different HCPCS codes were used before and after this time period.

scenarios: (a) if lower AWPs had been published for just the Dey products, (b) if lower AWPs had been published for just the Roxane products, and (c) if lower AWPs had been published for both Dey's and Roxane's products. I have been asked to assume that the lower AWPs for the Dey products, converted to per milligram units, would have been $1.64 for each product, and that the lower AWPs for the Roxane products, converted to per milligram units, would have been $1.70, $1.73, and $1.74 for the packages of 25s, 30s, and 60s, respectively. The results of re-calculating the medians in each of these scenarios is shown in the table below. The allowed amounts are for the KO and KP modifiers. I omit discussion about the calculation of the allowable amount for the KQ modifier, as that involves a slightly more complicated explanation and calculation that is unnecessary to the present discussion. For the convenience of the reader, I have highlighted in bold font the middle two prices that are averaged to establish the median.

Firm	**NDC**	**Original AWP**	**Alternative Dey AWP**	**Alternative Roxane AWP**	**Alternative Dey & Roxane AWP**
Compumed		3.22	**3.22**	**3.22**	3.22
Dey	49502-0685-03	3.53	1.64	3.53	1.64
Dey	49502-0685-60	3.52	1.64	3.52	1.64
Roxane	00054-8402-11	3.52	**3.52**	1.70	**1.70**
Roxane	00054-8402-13	3.52	3.52	1.73	**1.73**
Roxane	00054-8402-21	3.52	3.52	**1.74**	1.74
	Median	3.52	3.37	2.48	1.72
	Allowable (KP and KO)	$3.34	$3.20	$2.36	$1.63

40. In the above illustration, the effect of using lower AWPs for both the Dey and Roxane products would be to reduce the allowable amount from $3.44 to $1.63. This is a reduction of $1.57 and represents the amount of overpayment that would have occurred (with Medicare paying 80 percent) if both companies' AWPs were found to be improperly inflated as assumed above. In contrast, if one were to determine the effect separately for the two companies, the reduction would be $0.14 for Dey and $1.12 for Roxane. The sum of these is $1.26. Calculating the effect separately for each company would not result in a number that reflects the total impact on the Medicare program under the assumption stated above.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 23rd day of July, 2009.

Carolyn Helton

Carolyn Helton